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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,176	06/09/2005	Chikamasa Yama	04676.0184-00000	1747

22852 7590 06/08/2009

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EXAMINER	
OSTRUP, CLINTON T	

ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
06/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,176	YAMA ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/27/08 & 5/16/08*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/16/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed March 27, 2008 and the Information Disclosure Statement filed May 16, 2008. As directed by the amendment, claims 1-11 have been cancelled and claims 12-24 have been added. Thus, claims 12-24 are pending in this application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 12 requires inhalation by a user to perform the claimed functions. Thus, it is unclear if the "apparatus" claimed requires a human, or at least a human inhaling on the apparatus to meet the claimed limitations. If the claim requires a human to be inhaling on the apparatus, then it would be rejected under 35 U.S.C. 101 as being drawn to non-statutory subject matter (i.e. an inhalation of a user). However, for examination purposes this claim was read as having intended uses within the claim as indicated by the terms "for", "by", "to" and "such that."

Since the claims are drawn to an apparatus, and it has been held a recitation of the intended use of the claimed invention must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art, it is the examiner's position that an apparatus

having the same structure claimed, would inherently meet the intended use limitations claimed as the prior art structure would be capable of performing the intended uses claimed.

5. Regarding claim 19, the phrase "cake-like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "cake-like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05.

6. Claim 23 is confusing because it is unclear if the air-generated impact that "can be applied" to the pharmaceutical composition by outside air which is fed from the air inlet port into the inhalation flow path located upstream of the divider by an air inhalation of the user, is being applied or not. Since it can or cannot be applied, it is unclear how this adds any limitation to the claim.

7. Any remaining claims are rejected as depending from a rejected base claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 12-18 & 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerk et al. (5,301,666) in view of Gabrio et al. (6,615,826).

Regarding claim 12, Lerk discloses an inhalation device (figure 21) which can be used for transpulmonary administration comprising: a housing (figure 21); a mouthpiece

(10) provided at one end of the housing; a chamber (12 & 106) accommodated in the housing which can be used for containing a pharmaceutical composition which would be pulverized into fine particles by an air-generated impact which can be for dispersal in air; an air inlet flow path (right side with arrow pointing down), which upon inhalation of a user, would introduce into the chamber outside air (see arrows showing air flow coming into the housing and then into the chamber) and could be used for injecting outside air toward the pharmaceutical composition to apply an air-generated impact to the pharmaceutical composition; an inhalation flow path (down the center of the housing) having a suction port (port at 106 that connects the central chamber to the inhalation flow path) located inside the chamber to allow a user to inhale (when the mouthpiece is placed in a user's mouth and the patient inhales) the pulverized pharmaceutical composition; and an auxiliary flow path (just inside the outer walls of the mouthpiece and outside the walls of the mouth-side flow path (center tube in mouthpiece) with air inlet on either side at the bottom of the mouthpiece) for inhaling outside air which does not flow via the chamber, the auxiliary flow path opening around (the auxiliary flow path surrounds the inhalation flow path) the inhalation flow path in the direction of the air flow of the inhalation flow path.

However, Lerk does not specifically teach that the auxiliary air flowing out from the auxiliary flow path does not disturb the air flow of the inhalation flow path.

Gabrio teaches a mouthpiece (64 of Figure 11) with an air sheath (created by 66) wherein the auxiliary air flowing out from the auxiliary flow path (via 66) would not

disturb the air flow of the inhalation flow path (via the central tube). See: col. 6, line 64 - col. 7, line 10 and figure 11.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the mouthpiece with an angled air sheath as disclosed by Lerk by utilizing a mouthpiece with an air sheath that is parallel to the inhalation flow path in order to provide an air sheath at the extreme downstream end of the inhaler.

Regarding claim 13, Lerk discloses a mouthpiece (10) that is provided with a mouth-side flow path (inside center of mouthpiece) which communicates with the inhalation flow path (inside center of housing); the auxiliary flow path (just inside the outer walls of the mouthpiece and outside the walls of the mouth-side flow path (center tube in mouthpiece) with air inlet on either side at the bottom of the mouthpiece) that can be used for directly inhaling outside air that does not communicate (at least inside the device) with the inhalation flow path and the mouth-side flow path; and the inhalation device (figure 21) can be used for transpulmonary administration and is configured such that air-generated impact (arrows from right side go down and impact the composition in figure 21) is applied to the pharmaceutical composition by outside air which flows into the chamber (12 and 106) by inhalation-induced pressure generated when a user inhales air (from the mouthpiece), and the pulverized pharmaceutical composition is introduced to the mouth-side flow path, and at the same time outside air is directly introduced to the auxiliary flow path by the inhalation-induced pressure. See: arrows showing the flow of air into and within the apparatus in figure 21).

Regarding claim 14, Lerk discloses a mouthpiece (10) that is provided with a mouth-side flow path which communicates with the inhalation flow path and Gabrio teaches a divider (62 of figure 11 of Gabrio) having an orifice (65 of Gabrio) in at least one of the mouth-side flow path or the inhalation flow path that can be used for reducing the diameter of the flow path by forming a step part; and the inhalation device for transpulmonary administration is configured such that air-generated impact is applied to the pharmaceutical composition by outside air which flows into the chamber by inhalation-induced pressure generated when a user inhales air so that the pulverized pharmaceutical composition is introduced to the inhalation flow path and the mouth-side flow path, and also passes through the orifice.

Regarding claim 15, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have added additional dividers (62) with decreasing aperture sizes, such as the baffles in Figures 11a-11c of Gabrio, at spaced intervals in order to provide a sieve action that would only allow the finest particles to be inhaled by a user.

Regarding claim 16, Gabrio teaches a mouthpiece that is provided with a mouth-side flow path (inside center of mouthpiece) which communicates with the inhalation flow path (figures 1-2 & 6-7), and the auxiliary flow path that can be used for inhaling outside air is not used for applying air impact to the pharmaceutical composition, and does not flow via the chamber, and furthermore allows the inhaled outside air to flow into the mouth-side flow path through an air outlet (see arrows in figures 1-2 & 6-7 showing air flow) which opens into the mouth-side flow path, the air outlet opening in the

air discharge direction of the mouth-side flow path and being formed in a ring shape along the inner circumferential wall surface of the mouth-side flow path; and Lerk discloses the pharmaceutical composition as being pulverized by air impact generated by outside air flowing into the chamber (12) by inhalation-induced pressure that is generated when a user inhales air, and the pulverized pharmaceutical composition flows into the mouth-side flow path surrounded by outside air flowing into the mouth-side flow path from the ring-shaped air outlet. See: figure 21 of Lerk and figures 1-2 & 6-7 of Gabrio.

Regarding claim 17, Gabrio teaches a divider (62) having an orifice (65) that can be used for reducing the diameter of the flow path formed in the mouth-side flow path, wherein outside air containing the pulverized pharmaceutical composition passes through the orifice, and thereafter is surrounded by outside air flowing into the mouth-side flow path from the ring-shaped air outlet. See: Gabrio figures 1-2, 6-7, 9, and 11-11c.

Regarding claim 18, Gabrio discloses a flow-path length of the orifice that is elongated in the air discharge direction of the mouth-side flow path by an elongated mouthpiece.

Regarding claim 20, Lerk discloses a check valve (111) which can be used to prevent the pulverized pharmaceutical composition from flowing from the air inlet flow path to the outside.

Regarding claim 21, Gabrio teaches a divider (62) for dividing the inhalation flow path, the divider having an orifice (65) for reducing the diameter of the inhalation flow

path and being located downstream of the air inlet port, and Lerk discloses a housing (figure 21) that comprises a main body (109) formed cylindrically and a vessel (1) provided detachably at the end of the main body; the chamber (12) is formed by the vessel and can be used for containing a pharmaceutical composition which is pulverized into fine particles by an air-generated impact for dispersal in air; and the inhalation flow path is formed from the inner side space (see arrows to right of apparatus entering the apparatus and flowing downward in figure 21) of the main body, the mouth piece (10) and the vessel, the inhalation flow path being for flowing outside air containing the fine particles of the pharmaceutical composition from the vessel-side toward the mouthpiece-side.

Regarding claim 22, Lerk discloses the air inlet port (right side with arrow pointing down) s formed between the main body (109) and the vessel (1) by means of a notch (between mouthpiece and main body where air enters) provided at the end of the main body; and Gabrio teaches an auxiliary flow path that formed between the mouthpiece (64) and the divider (62) means of a notch (where air enters 66) formed at the outer circumferential surface of the divider. See: Lerk figure 21 and Gabrio figures 11-11c.

Regarding claim 23, Lerk discloses as inhalation flow path (inside center of housing) that has such a capacity (size) that an air-generated impact (air flow) "can be applied" to the pharmaceutical composition by outside air which is fed from the air inlet port (see arrows showing airflow in figure 21) into the inhalation flow path located upstream (right side of apparatus where air enters as shown by arrows) of the modified device with a divider (62 of Gabrio) by an air inhalation of the user.

Regarding claim 24, Gabrio teaches an auxiliary flow path (figures 1-2 & 6-7) that is provided with an air outlet (see arrows showing airflow into mouthpiece) which opens into the inhalation flow path of the mouthpiece; and the air outlet is provided at such a position that outside air flowing in from the air outlet is inhaled into the mouth of the user without passing through the orifice (when the divider 62 is positioned upstream from the end of the mouthpiece). See: figures 1-2, 6-7 & 11-11c of Gabrio.

10. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lerk et al. (5,301,66) in view of Gabrio et al. (6,615,826), as applied to claim 12 above, and further in view of Horlin (2001/0020472).

The combined references disclose all the limitations of claim 19, and Lerk discloses rotating the device to obtain access to each of the chambers (12); however, the combined references do not explicitly teach the unsealing member for releasing the sealed condition of a vessel provided by a sealing member, wherein the vessel is unsealed by the unsealing member to establish communication between the chamber and the inside of the vessel.

Horlin teaches a capsule opening arrangement for use in a powder inhaler wherein a vessel (11) is opened with an unsealing member (14 for releasing the sealed condition of a vessel (11) provided by a sealing member (outer portion of capsule), wherein the vessel is unsealed (opened) by the unsealing member (14) to establish communication between the chamber and the inside of the vessel (11).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the disk containing metered dosage (12) opening

system disclosed by Lerk by utilizing the capsule containing metered dosage opening and delivering system as taught by Horlin in order to provide a medicament delivery device that could be quickly and easily refilled using conventional cheap capsules that could be filled with a variety of medicaments.

Response to Arguments

11. Applicant's arguments with respect to claims 12-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gieschen et al. (2001/0027790) and Harris (3,998,226) which are both drawn to inhalers with air sheaths.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771